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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,290	03/03/2004	Frank S. D'Amelio SR.	45437	3540

1609 7590 07/13/2007

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,290	D'AMELIO ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,9, 11-14 and 16-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,9-14 and 16-33* is/are rejected.

7)☒ Claim(s) *1-3, 5-7, 9, 11-14, 16-17 and 30-33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed March 30, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Upon further consideration, the previous indication of allowable subject matter has been reconsidered.

Declaration under 37 CFR 1.131

The Declaration filed on April 18, 2007 under 37 CFR 1.131 is not sufficient to overcome the US Patent Application Publication 2005/015852 reference. The Declaration is not sufficient because it is specific to one composition comprising the components in claim 10. It appears to overcome the rejection in regards to claims 12-13, 17, 20-25 and 27-28 because they comprise the specific compounds disclosed.

Claims

Claim Objections

1) Claims 1-3, 5-7, 9 and 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite the phrase "in an amount effective to inhibit inflammation of oral tissue",

which does not further limit the claims because they recite a percent range in which the *Centipeda* component is incorporated into the composition.

2) Claims 12-14, 16-17 and 30-33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite the phrase "in an amount to inhibit inflammation of oral tissue and promote cell renewal", which does not further limit the claims because they recite a percent range in which the *Centipeda* component is incorporated into the composition.

3) Claim 26 is objected to because of the following informalities: the term "further" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112 -Indefiniteness (New Rejection)

Claims 1-3, 5-7, 9-14, 16-25 and 26-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 1-3, 5-7, 9, 11 and 16 recite the limitation "a holistic extract". This phrase is not defined in the specification and the modifying function of the "holistic" is not clear. Therefore it is not clear how a "holistic extract" is different from an "extract".

2) Claims 12-14, 16-25 and 27-33 recite the limitation "a bioactive agent". There is no clear line of demarcation between the bioactive agent and the recited extract, which is also a bioactive agent.

3) Claims 9-10, 17-18, 26 and 32 recite the phrase "chlorophyll KK". This phrase is not defined in the specification and the modifying function of the "KK" is not clear.

4) Claims 9 and 17 recite the phrase "bio-saponin concentrate". This phrase is not defined in the specification is not clear how or to what degree the claimed component is "concentrated".

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

3) Claims 1, 4-5, 8-9, 11-13, 15, 17, 20-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romanowski et al (US 2005/0158252). The rejection is maintained in regards to claims 1, 5, 9 and 11. The rejection is withdrawn the case of claims 12-13, 17, 20-25 and 27-28.

Applicant argues Applicants are preparing under 37 C.F.R. 1.131 establishing a date of conception and reduction to practice the invention a Declaration. This argument is not persuasive.

The Declaration does not disclose the incorporation of vitamin E, which is a component in the claims 1, 5, 9 and 11.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 1-3, 5-7, 9, 11, 12-14, 16 and 22-25 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Lawlor (US 2003/0198604).

Close discloses an aqueous alcoholic extract from plant genus *Centipeda* in an orally acceptable carrier in the oral treatment of medical conditions that include treatment of rashes, allergic reactions, inflammations, bacterial infections or gastrointestinal disorders, which encompasses the pertinent method claims wherein bacteria growth and inflammation are treated. The compositions comprise *Centipeda cunninghami*, as recited in claim 5, which is obtained by extraction of dried plant material with aqueous ethanol, comprising 30% ethanol/70% water or a range of strengths. The amount of the extract may range from 2.1% to 20% of the composition. In oral compositions, the extract may be combined with one or more of the following abrasives, solvents, humectants detergents, binders, herbal actives e.g. aloe vera; essential oils such as eucalyptus oil and peppermint oil, deordorizing agents and suspending agents (paragraphs 0014-0015). Chamomile may also be used in the compositions. Although it is not disclosed in an oral composition, it is an ingredient used in oral compositions as a wound healing and inflammation-inhibiting agent[1]. Chlorophyll is included in the toothpaste composition. The compositions may be delivered orally in

[1] Klueppel et al., US 5,145,665, col. 4, lines 14-17.

the form of a tablet, mouthwash, mouth gel, mouth lotion, gargle solution and toothpaste. The instant claims uses the term about 0.5 to 1% of *Centipeda* which encompasses 2.1%, encompassing claim 2. The lavender oil may also be used in the compositions. The aloe vera content ranges from 6% to about 25%. The reference differs from the instant claims insofar as it does not disclose using folic acid or coenzyme Q10 in the compositions.

Lawlor discloses oral compositions for dental care. The reference is used as a general teaching to show the ingredients used in oral products. Clove bud oil is an essential oil used as a flavoring, vitamins include folic acid, antioxidants include vitamin E, and nutritional supplements include coenzyme Q10 (paragraphs 0077-0078). These ingredients comprise preferably from 0.01% to 10% by weight of the compositions (paragraph 0060), which encompasses the concentrations in the bioactive agent as well as the composition. The reference differs from the instant claims insofar as it does not disclose aloe vera or *Centipeda* extract are in the compositions.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used Clove bud oil, folic acid, vitamin E, and coenzyme Q10 in the compositions of the primary reference motivated by the desire to use the components

for their known function, such as flavoring, antioxidant and nutritional function, as disclosed by the secondary reference and supported by cited precedent.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to determine workable conditions, i.e., concentration, motivated by the desire to obtain optimal results, as supported by cited precedent.

2) Claims 1-7, 9, 11, 12-17, 19-20, 22-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Masterson et al. (US 6,200,550).

The primary reference, Close, is discussed above in subsection 1. The reference differs from the instant claims insofar as it does not teach using folic acid and coenzyme Q10 in the compositions or vitamin E for an oral composition.

Masterson et al. disclose oral compositions comprising coenzyme Q10, folic acid and vitamin E. The disclosed oral care compositions are used for treating and ameliorating the symptoms of gingivitis and periodontal disease. The compositions comprise coenzyme Q10 combined with a solubilizing agent. The solubilizing agent is capable of fully solubilizing coenzyme Q10 in water based oral care composition and is pharmaceutically acceptable (col. 4, lines 11-21), which encompasses the instant claims. Dental studies in humans have demonstrated a deficiency of coenzyme Q10 in

the gingiva tissues of individuals with gum disease and clinical studies have shown that coenzyme Q10 improved diseased gingiva tissues and a decrease in sub-gingival microbes has been observed, which encompasses the method claims' criteria of inhibiting bacteria growth (col. 1, lines 31-44). The coenzyme may be included in the compositions at concentrations ranging from 0.001% to 20% depending on the type of composition such as mouthwash or toothpaste (col. 4, lines 42-56), as recited in claims 2, 7, and 27. The compositions may also include other active ingredients, such as, anti-bacterials from 0.1% to 5% (col. 7, lines 7-8), anti-inflammatory agents and healing agents in the amounts of about 0.01% to about 10% (col. 7, lines 34-37). Also included are glycerin and flavors such as peppermint oil and spearmint oil. The reference differs from the instant claims insofar as it does not disclose the composition comprises an extract of *Centipeda* genus and aloe vera.

In regards to the amounts of claim 1, it cannot be determined what the final concentrations of the components are because it is not disclosed how much bioactive agent is in the composition. It would have been obvious to one of ordinary skill in the art to determine workable conditions, i.e., concentration, motivated by the desire to obtain optimal results, as supported by In re Aller cited above.

It would have been obvious to one of ordinary skill in the art to have used the folic acid, coenzyme Q10 and vitamin E in the compositions of the primary reference motivated by the desire to use the components for their known function, such as flavoring, antioxidant and nutritional function, as disclosed by the secondary reference

and supported by Sinclair & Carroll Co. v. Interchemical Corp., In re Linder, and In re Dial, cited above.

3) Claims 1-3, 5-7, 9-14 and 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Harrison (The Periodontal Solution: Healthy Gums Naturally) and Rice et al. (US 5,741,138).

The primary reference, Close, is discussed above in subsection 1. The reference differs from the instant claims insofar as it does not teach using folic acid, coenzyme Q10, oregano oil, clove bud oil, bio-saponin, prickly ash bark extract, Echinacea extract, gotu kola extract, olive leaf extract, black walnut hull extract, grapefruit seed oil and green tea extract in the compositions or lavender oil, thyme oil, calendula extract, and vitamin E in an oral composition although they are disclose by the reference for other compositions.

Harrison discloses components used in oral compositions that improve the health of teeth and gums. These components include folic acid which converts amino acids (page 96); aloe vera regenerates cells and reduces inflammation (page 95); coenzyme Q10 repairs and maintains periodontal tissue (page 99); oregano oil is a anti-bacterial, anti-viral and anti-fungal (page 104); clove bud oil is and antibacterial, antiseptic, analgesic, bactericidal, antioxidant and anti-inflammatory agent; bio-saponin forms emulsions and may be used in place of highly irritating sodium lauryl sulfate (page 97); prickly ash bark extract increases capillary circulation (page 105); Echinacea extract stimulates certain cells to produce new connective tissue (page 100); gotu kola extract

promotes rapid wound healing by accelerating tissue growth (page 101); olive leaf extract anti-bacterial, anti-viral and anti-parasitic (page 103); black walnut hull extract kills parasites (page 97); grapefruit seed oil is an anti-bacterial, anti-viral and anti-fungal (page 101); lavender oil is an antiseptic, antimicrobial and anti-inflammatory agent(page 102); thyme oil is an anti-microbial agent (page 106); calendula extract is an anti-fungal and reduces inflammation (page 99); eucalyptus oil is an anti-microbial agent (page 101); peppermint oil is an anti-carcinogenic, anti-parasite and anti-inflammatory agent (page104); *Centiepeda cunninghami* is an anti-viral and anti-inflammatory agent (page 104); plant enzymes are used to improve bioavailability of other supplements (page 105); and vitamin E has wound healing properties, is an antioxidant and improves circulation (page 100). The reference differs from the instant claims insofar as it does not disclose the components are used together in one composition, green tea extract or the amounts that may be used in an oral composition.

Rice et al. discloses oral compositions and is used as a general teaching disclosing components used in oral compositions. Green tea is used as an antiplaque/antigingivitis agent. Clove oil and peppermint oil may be used as flavors. The reference differs from the instant claims insofar as it does not disclose using folic acid, coenzyme Q10, oregano oil, bio-saponin, prickly ash bark extract, Echinacea extract, gotu kola extract, olive leaf extract, black walnut hull extract, grapefruit seed oil, lavender oil, thyme oil, calendula extract, and vitamin E in the compositions.

It would have been obvious to one of ordinary skill in the art to have used the folic acid, coenzyme Q10, oregano oil, clove bud oil, bio-saponin, prickly ash bark

extract, Echinacea extract, gotu kola extract, olive leaf extract, black walnut hull extract, grapefruit seed oil, green tea extract in the compositions or lavender oil, thyme oil, calendula extract, and vitamin E in the compositions of the primary reference motivated by the desire to use the components for their known function, such as flavoring, anti-microbial, blood circulatory, antioxidant and nutritional function, as disclosed by the secondary and tertiary references and supported by Sinclair & Carroll Co. v. Interchemical Corp., In re Linder, and In re Dial, cited above.

Claims 1-3, 5-7, 9-14 and 16-33 are rejected.

Claims 1-3, 5-7, 9, 11-14, 16-17 and 30-33 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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